

Remarks:

Reconsideration of the application is requested. Claims 1, 4-10, 13, 15, 19, 21-22, and 25-40 are now in the application. Claims 1, 4, 8, 15, and 21-22, and 25 have been amended. Claims 30-40 have been added.

A typographical error was found in the cross-reference section of the specification. The amendment to paragraph [0001] corrects this error.

To begin, claims 30-40 have been added to expand the scope of the device that encompasses more of the embodiments of the invention. For the reasons specified below, these claims do not add new matter and the features are supported by the specification.

The invention generally involves an implant for a joint between two bones. The implant has a first surface that abuts a first bone of the joint and a second surface that abuts the second bone of the joint. The implant is moved between at least two positions. The different positions are narrow and wide and cause the bones to move relative to each other.

In one preferred embodiment, the implant is rotated about an axis to move the implant from the narrow position to the wide position. It is unnecessary to use the implant as a wedge or screw that splits the bone as in an osteotomy. The implant does not move axially as it is rotated from the narrow to wide position. The specification shows these features in Figs. 14-15 and 18-20. *See also* the specification paragraph [0092] through [0106].

Another feature being introduced in this amendment is the nested screws; *see* claim 38. Support for this feature is in, for example, in Figs. 8-11, and 17.

Another feature being claimed is that the implant is being affixed (i.e. fastened) to one and only one of the bones; *see* claim 41. Support for this feature can be found in the specification in paragraph [0008] of the specification.

In the penultimate paragraph of page 2 of the Office action, the Examiner rejected claims 1, 8-9, 13, 15, and 19 as being unpatentable over Stone '433 in view of Michelson '635 and Kovaleva et al. '993 under 35 USC § 103(a).

Stone '433 teaches an osteotomy wedge. Osteotomies are orthopedic procedures in which one bone (i.e. the tibia) is straightened to reduce bowing or knock-kneedness. Stone '433 teaches making an incision in the bone, inserting an osteotomy pin 260 in the incision. A wedge shaped osteopathy device 200 with a leading edge is used. The leading edge of the device has a channel leading to a trailing edge. The device is placed on the osteotomy pin and driven (i.e. wedged) into the incision. Once in place, the device is secured to the bone by screw 176 in a plate on the trailing edge. The heads of the screws extend beyond the plate.

In contrast to Stone '433, claim 30 of the instant application describes a device for changing the spatial relationship between two bones that form a joint. Claim 32 describes a device that moves to a wide position not by moving along an axis of incision (i.e. not along an osteotomy pin). Claim 36 further describes the channel and fastener as passing from the side (i.e. rear) surface to the first (i.e. superior or inferior) surface. Claim 37 describes that the fastener in the channel is nested. Claim 41 teaches that the implant is attached to only one of the abutting bones.

Michelson '635 does not teach or suggest the features of the invention according to claim 30. Michelson '635 teaches a device that changes the relative position of two bones by moving the changing the distance between the abutting surfaces (i.e. Fig. 30). Second, in contrast to claim 36 of the instant application, Michelson '635 does not teach a fastener that passes from the side surface through a surface abutting the bone. The screw 718 in Michelson '635 does only passes through the side wall. Furthermore, the screw 718 is not a "fastener" for the abutting bone. The device of Michelson '635 shows the same interface between both surfaces and the respective bone; so in contrast to claim 41 of the instant application, Michelson only teaches devices that are affixed to both bones or to neither of the bones, but not only one of the bones.

Kovaleva '993 teaches another wedge device for osteotomy (c. 3, l. 35) that works by being forced axially between two bones. Kovaleva '993 does not teach a device for changing the spatial

relationship between two bones of a joint. Rather, Kovaleva '993 teaches an osteotomy device for compensating for missing bulk in a bone forming a bowing bone; *see* col. 4. In contrast to claim 36 of the instant application, the screw 12 only passes through the flange (crescent shaped base 6) but not through the surface that the bone abuts 4 or 5. *In arguendo*, even if the screw 12 were considered to meet the features of claim 36, Kovaleva et al. clearly does not teach a further fastener as described in claim 21 of the instant application for attaching through the second surface of the device into a second bone.

Because Stone '433 in view of Michelson '635 and Kovaleva et al. '993 fail to teach a device for changing the spatial relationship between two bones (in contrast to one bone in an osteotomy) that moves the bones from a narrow position to a wide position without changing the spacing of the surfaces within the device, claim 30 of the instant application is patentable over the prior art.

A Declaration under Rule 1.132 is attached. The Declaration is made by the inventor who is one with more than ordinary skill in the art. The Declarant is on the faculty of more than one medical school and is the inventor named in at least 159 U.S. patents. The Declarant explains why one with ordinary skill in the art would not consider an osteotomy device when creating a device for spacing the bones in a joint. This evidence explains why the Examiner should not base rejections for a joint device on osteotomy devices such as those taught in Stone '433 and Kovaleva '933.

Even if Stone '433 and Kovaleva '933 are considered, Claim 25 is patentable over Stone '433 in light of Michelson '635 and Kovaleva '933 because no *prima facie* case of obviousness was made by the Examiner. When making the rejection, Stone showed an osteotomy device. The osteotomy device teaches a first fastener attaching to one given bone on the device's superior surface and a second fastener to the same bone on the device's inferior surface. Michelson '635 teaches no such fastener. Kovaleva '993 teaches fasteners that only attach to one bone on only one surface (i.e. either the superior surface or the anterior surface, but not both). Because, the prior art fails to teach or suggest a device that attaches to a first and a second bone, claim 25 is not obvious in light of the prior art. Likewise, claims 26-29, which depend on claim 25, are also not obvious.

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Examiner: Hoffman, Mary C.

Applicant reemphasizes that the invention according to claim 32 of the instant application is particularly different than the prior art. Claim 32 describes a device that is placed into a joint along an axis but then does not expand the joint by moving along that axis. This motion should distinguish the device according to invention from any prior-art wedges or screws.

Applicant also reemphasizes that the fastener that is inserted in a channel from the side surface to one of the surfaces about the bones is a further patentable device.

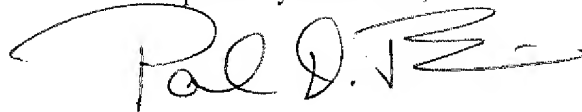
Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$25 is attached to provide for one additional total claim.

No additional fee is believed due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A02-021-5).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Paul D. Bianco", with a stylized flourish extending from the end.

Paul D. Bianco, Reg. No. 43,500

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